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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,832	08/28/2001	Michele A. McTigue	0125-0016D2	3870

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AGOURON PHARMACEUTICALS, INC.
10350 NORTH TORREY PINES ROAD
LA JOLLA, CA 92037

EXAMINER
KIM, YOUNG J

ART UNIT	PAPER NUMBER
1637	11

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/939,832	MCTIGUE ET AL.	
	Examiner	Art Unit	
	Young J. Kim	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-27* is/are rejected.

7)☒ Claim(s) *17 and 24-27* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence Compliance Notice* .

DETAILED ACTION

Sequence Rules

This application contains sequence disclosures that are encompassed by the definition for nucleotide and/or amino acid sequences set for in 37 CFR 1.82(a)(1) and (a)(2). For example, page 10, 5th paragraph, recites oligonucleotide sequences without their SEQ ID Numbers. Therefore, this application fails to comply with the requirement of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotides Sequences And/Or Amino Acid Sequence Disclosures. Appropriate correction is required.

Claim Objections

Claims 17, 24, 25, and 26 are objected to because of the following informalities:

Claims 17, 24, 25, and 26 recite the acronyms, "RTK," "PDGFR," and "VEGFR," respectively, without first identifying them. Amending the claim to recite the phrase, "Receptor Tyrosine Kinase," "Platelet Derived Growth Factor Receptor," and "Vascular Endothelial Growth Factor Receptor," respectively, would obviate this objection.

Appropriate corrections are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17-27 recite the limitation "evaluating the interaction between ***the kinase domain*** of said modified RTK polypeptide" in sub-step (c). There is insufficient antecedent basis for this limitation in the claim because it is indefinite whether the term, "the kinase domain" refers to the truncated kinase insert domain, kinase domain α helix D, or kinase domain α helix E. For the purpose of prosecution, the term is assumed to mean "truncated kinase insert domain."

Claims 23, 25, and 26 recite the limitation "said RTK polypeptide." There is insufficient antecedent basis for this limitation in the claim. For the purpose of prosecution, the claim is assume to mean, "said modified RTK polypeptide."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 17-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Williams et al. (U.S. Patent No. 6,043,211, issued March 28, 2000, filed June 5, 1995).

Claims are drawn to a method of identifying compound which interact with kinase domain of a modified RTK polypeptide, wherein said modified RTK polypeptide comprises truncated Kinase Insert Domain (KID).

Williams et al. disclose a modified PDGFR-β (claim limitation 23-24) and its method of evaluating drugs for their physiological activity (column 2, lines 20-28; column 6, lines 5-10; column 46, lines 20-28; claim limitation 1-b and 1-c). The modified PDGFR-β is interacted with PI3 kinase, wherein said modified PDGFR-β comprises deletion of the kinase insert (KI) region (or Kinase Insert Domain) (column 46, lines 23-25; claim limitation 19). Method of producing the polypeptide via use of a host cell comprising a DNA construct is disclosed (column 5, lines 55-68; claim limitation 1-a). Williams et al. discloses that direct structural determination via x-ray crystallography or 2D-NMR can be used to determine locations of interactions, which guide where the modifications are likely to affect interactions, both ligand and effector binding activities (column 30, lines 60-65; claim limitation 18), demonstrating that the polypeptide is suitable for x-ray crystallography (claim limitation 1-a). The modified polypeptide is disclosed as retaining its tyrosine kinase acitivity, evidencing that the kinase domain is of sufficient length to maintain conformation associated with kinase structure (column 46, line25; claim limitation 22).

Therefore, the invention as claimed is obvious over the cited reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams et al. (U.S. Patent No. 6,043,211, issued March 28, 2000, filed June 5, 1995).

Claims 20 and 21 further limits the method of claim 17 by reciting the number of amino acid residue deletions from the KID domain.

The modified PDGFR-β is interacted with PI3 kinase, wherein said modified PDGFR-β comprises deletion of the kinase insert (KI) region (or Kinase Insert Domain) (column 46, lines 23-25).

Williams et al. do not explicitly disclose the specific number of amino acid residues deletion from the KID domain.

It would have been obvious to one of ordinary skill in the art the time the invention was made to modify the number of amino acid residues deletions in the KID domain in the method disclosed by Williams et al. to arrive at the invention as claimed, because such modification, while not explicitly taught, would have been necessary to be able to arrive at the modified PDGFR-β which retained its tyrosine kinase activity.

In *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342 (CCPA 1968), the court expressed that, "in considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inference which one skilled in the art would reasonably be expected to draw therefrom."

Therefore, the requirement of such step would be well known to one of ordinary skill in the art of mutagenesis, rendering the claims obvious over the cited reference.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25 and 26 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 09/939,833, 09/939,832, and 09/939,754. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

Claims 25 and 26 of the instant application is drawn to a method of identifying compounds which interact with the kinase domain of a modified RTK polypeptide, wherein the claims further limit the RTK polypeptide as being VEGFR-2 polypeptide. Claim 3 of the '833, '832, and '754 application (all identical to each other) is an independent claim drawn to a method of identifying compounds which interact with the kinase domain of a modified VEGFR-2 polypeptide, thus overlapping in scope. Only notable difference between the claims of the instant application and the claim of the '833, '832, and '754 application is that the claim of the

instant application recites that the modified VEGFR-2 polypeptide comprises a deletion in its KID region while the claim of the '833, '832, and '754 application does not. However, the only working embodiment of the modified VEGFR-2 polypeptide of the '833, '832, and '754 application is drawn to that which comprises, "deletion of various amino acid residues from an area of the catalytic region called the kinase insert domain (KID)" [0001], thereby rendering the claims of the instant application obvious over claim 3 of the '833, '832, and '754 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Claims 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitation of the base claim and any intervening claims.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (703) 308-9348. The Examiner can normally be reached from 8:30 a.m. to 7:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (703)-308-3905. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. The Fax number is (703) 746-

3172. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Young J. Kim

8/1/03

KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

8/4/03

Application No.:09/939,832

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [ ] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [ ] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [X] 7. Other: The oligonucleotide sequences in page 10 are not defined by their SEQ ID Numbers.

Applicant Must Provide:

- [X] An initial or **substitute** computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or **substitute** paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856